DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2014

Sun Nuclear Corporation
% Mr. Jeff Kapatoes
Sr. Director Product Management
3275 Suntree Boulevard
MELBOURNE FL 32940

Re: K141800
Trade/Device Name: PerFRACTION (Model 1215)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 30, 2014
Received: July 3, 2014

Dear Mr. Kapatoes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

## 510(k) Number (if known):____ K141800_____

## Device Name: Model 1215 PerFRACTION

## Indications for Use:

PerFRACTION is intended to allow for the detection of errors that can occur in the delivery of a patient's radiation therapy treatment.

PerFRACTION allows for the comparison of the cumulative exit image(s) for one treatment fraction to the cumulative exit image(s) for another treatment fraction, thus providing a consistency check on the delivery of the treatment fraction.

Perscription Use ____X_____ (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use ___ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

_____

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)_____K141800_____

# 510(k) Summary K141800

Provided in accordance with 21 CFR 807.92 (c)

## 1 General Provisions

Date Prepared:

June 30, 2014

Submitted by:

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Web: www.sunnuclear.com

Contact Person:

Jeff Kapatoes
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Common Name:

Quality Assurance for Patient Radiation Treatment

Trade Names:

Model 1215 PerFRACTION™

Establishment Registration Number:

1038814

Classification:

Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Product code: IYE

Predicate Device:

| | |
|---|---|
| Model Name: | COMPASS |
| Common Name: | Accelerator, linear, medical |
| 510(k) # | K072374 |
| Manufacturer: | Scanditronix Wellhdfer GmbH |
| Cleared: | Dec 7, 2007 |

## 2 Description:

PerFRACTION™ is a device that includes software installed on standard, modern computing hardware (provided with the software) that allows clinicians to perform quality assurance for each fraction of a radiotherapy treatment plan. PerFRACTION compares the beam-exit measurement data from a treatment fraction to data from a prior baseline fraction. This comparison allows for the detection of errors that may occur with the delivery system such as the multi-leaf collimator, accelerator, and collimating jaws.

## 3 Intended Use Statement:

Model 1215 PerFRACTION is intended to allow for the detection of errors that can occur in the delivery of a patient's radiation therapy treatment.

PerFRACTION allows for the comparison of the cumulative exit image(s) for one treatment fraction to the cumulative exit image(s) for another treatment fraction, thus providing a consistency check on the delivery of the treatment fraction.

## 4 Technological Characteristics

PerFRACTION™ utilizes the output from the electronic portal imaging device (EPID) that is part of the treatment delivery device to perform a consistency check between fractions, while the predicate uses an array of ionization chambers. The EPID confers the advantage of having very high density detectors (0.4 mm spacing or less) while the predicate offers the use of ionization chambers. The latter item is not viewed as significant as PerFRACTION performs a consistency check fraction-to-fraction and does not convert EPID signal to dose.

## 5 Performance Data

PerFRACTION™ has been tested in non-clinical and clinical settings, and it has been shown that this device performs within its design specifications. Performance testing involved assessment of the device when exposed to errors in the collimation jaws, multileaf collimator leaves, accelerator output, and gantry rotation of the treatment delivery device. Based on the results of this performance testing when evaluated against published data for the predicate, Model 1215 PerFRACTION is as safe, as effective, and performs as well or better than the predicate device.